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OVERVIEW

Background

On December 18, 2002, Commissioner of Food and Drugs, Mark B. McClellan, M.D., Ph.D., announced a major new initiative to make available more and better information about foods and dietary supplements, to help American consumers prevent diseases and improve their health by making sound dietary decisions. The Consumer Health Information for Better Nutrition Initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements: to encourage makers of conventional foods and dietary supplements to make accurate, up-to-date, science-based claims about the health benefits of their products, and to help eliminate bogus labeling claims by pursuing marketers of human dietary supplements and others who make false or misleading claims about the health benefits or other effects of their products. Through these objectives, the agency seeks to help consumer improve their understanding of how their dietary choices may influence their health, to promote competition among product developers to find better ways to help improve health through better diets, and ultimately to prevent serious and life-threatening diseases through better dietary choices by Americans.

Health and Human Services Secretary Tommy G. Thompson said, "By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can help empower consumers to make smart, healthy choices about the foods that they buy and consume."

The future of nutrition and diet/disease relationships is evolving very rapidly. Science is exploring opportunities for improving the health consequences of nutrition that range from a better understanding of the impact of general dietary patterns for the US population as a whole to the specific understanding of how an individual's genetic makeup interacts with food and the environment – "nutritional metabolomics" – increasing the ability to "design" foods and diets for individuals to maximize health. The Consumer Health Information for Better Nutrition Initiative

is at the forefront of this evolution. It is designed to encourage the kind of marketplace where healthy foods can compete readily among all foods available; to foster research and better understanding about diet and health; and to protect consumers, and to help consumers protect themselves, from misleading claims by producers of foods and dietary supplements about health benefits that are not supported by science.

The agency is aware that there are many opportunities to greatly improve public health beyond those that have been traditionally associated with the product approval and enforcement activities of the FDA. These opportunities have much to do with assisting the public in making wise dietary choices that benefit long-term health. When FDA's mission is properly understood to include this role, a number of possible strategies become evident. For example, challenging the industry to channel competitive energies into disseminating health information in food labeling and promoting food products on the basis of nutritional value, as well as simply taste, price, and amount. The agency also sees the possibility to pursue a range of consumer information options in collaboration with other federal agencies, health researchers, and stakeholders as more information about substance/diet relationships becomes available. Thus, this report represents only the first concrete step in a larger and more far reaching program to improve public health.

Health messages on product labels that may influence consumer knowledge and hence dietary choices fall into three major categories. Agency policies on all three may have important consequences for consumer behavior. First, "health claims" have a different definition and regulatory provisions compared to other types of claim statements on conventional foods and dietary supplements. Health claims are specifically about the relationship between a substance and a disease, and they are reviewed and authorized by the FDA. An example of a health claim related to the disease osteoporosis is: *Calcium may reduce the risk of osteoporosis*. Second, "structure/function" claims are also allowed on foods, but make no reference to disease. Instead, they highlight how the food substance works within or otherwise supports the body. An example of a structure/function claim would be: *Calcium helps build strong bones.* These structure/function statements are not pre-reviewed by FDA but must be truthful and substantiated and not misleading. Though the statutory standards for

structure/function claims differ from health claims, they too may affect consumer behavior and thus assuring their accuracy is another important element for effective regulation of product claims for consumers. Finally, truthful and non-misleading general "dietary guidance" statements can also be made on food labels without FDA review. These statements, unlike health claims which target a specific substance and a certain disease, focus instead on general dietary patterns, practices, and recommendations that promote health. An example would be the "5-a-Day" program from the National Cancer Institute (NCI), which encourages the consumption of fruits and vegetables for better health. Such general guidance can help encourage better nutrition.

The Consumer Health Information for Better Nutrition Initiative has as its central focus improving the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. A better-informed public, supported by effective, science-based regulation of health information, would be expected to make better nutritional choices. Such regulation would also encourage food and dietary supplement producers to compete in ways that better protect the public from disease risks. As part of this Initiative, the FDA Task Force on Consumer Health Information for Better Nutrition (the Task Force) recommends that FDA use interim procedures and an interim evidence-based ranking system for qualified health claims on food labels (including conventional human food and dietary supplements).

Health claims are voluntary statements on food labels that were authorized by the 1990 Nutrition Labeling and Education Act (NLEA). They are intended to assist consumers in understanding the relationship between a substance in a conventional food or dietary supplement and its ability to reduce the risk of contracting the disease in healthy populations. They were put in place by Congress so that food manufacturers could voluntarily, by use of the food label and labeling, let consumers know about important beneficial food components that had the ability to reduce disease risk when integrated into the total daily diet. Health claims are not drug claims, which by law focus on diagnosing, treating, curing, or mitigating disease. Rather, health claims address the reduction of risk as part of a total diet. There is more evidence than ever that dietary choices have major impacts on population health. For

example, researchers have indicated that changes in diet could lead to a significant reduction in chronic diseases such as heart disease.

As part of the 1990 NLEA, Congress gave FDA the option of establishing a different standard for health claims for dietary supplements labels as compared with that which Congress had provided for conventional foods. FDA determined that the best course of action was to use the same standard for both dietary supplements and conventional foods. This decision was motivated by public health considerations: All consumers eat conventional foods and most use dietary supplements; inconsistent standards would lead to consumer confusion and biased consumption choices. So, current regulations for health claims apply equally to dietary supplements and conventional foods.

In setting the rules for health claims, Congress provided for FDA to authorize health claims when the agency determined, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement (SSA), among experts qualified by scientific training and experience to evaluate such claims that the claim is supported by such evidence. Under existing regulations, health claims are put in place through a petition process by which FDA reviews the science in support of and against the claim, and determines whether to authorize the claim through notice-and-comment rulemaking.

The NLEA required that FDA itself initially consider health claims for ten substance/disease relationships. FDA determined that there was significant scientific agreement concerning a number of these specified substance/disease relationships and in turn authorized eight claims. Not all relationships that Congress specified to be reviewed were found to meet the standard of significant scientific agreement. Accordingly, not all were authorized by FDA.

Dietary factors and sedentary lifestyles contribute substantially to the burden of preventable illnesses and premature deaths in the United States. Indeed, dietary factors are associated with 4 of the 10 leading causes of death: coronary heart disease, some types of cancer, stroke,

and type 2 diabetes.[1] For example, high blood cholesterol is a major risk factor for coronary heart disease that can be modified by diet and other factors. Lifestyle changes that prevent or lower high blood cholesterol include eating a diet low in saturated fat and cholesterol, increasing physical activity, and reducing excess weight.[2] Fat intake in the United States as a proportion of total calories is lower than it was many years ago, but most people still eat too much saturated fat.[3]

There is growing evidence of a public health gap in knowledge and behavior with respect to substance/disease relationships. According to the recent Sloan State-of-the-Industry Report published in *Food Technology* (Top 10 Trends to Watch and Work On, April 2003), consumers have no problems holding dichotomous attitudes about the pleasures of food and its power to influence their health. As more shoppers acknowledge indulging their cravings, more of them also admit that what they eat can have a major effect on how healthy they feel.

The most recent Food Marketing Institute (FMI, 2002) Trends in the United States Survey indicated that the percentage of consumers who recognize the importance of eating healthfully and who are interested in trying foods that may improve their health is increasing. 86% *agree* or *strongly agree* that "in most cases, eating healthfully is a better way to manage illness than medications," up from 76% in 2001. 54% said they are *very interested* in trying health-promoting foods. 51% want products designed to help them with high blood pressure and diabetes; 50% with allergies; 49% with weight control; 41% with osteoporosis; 40% with arthritis, and 40% (women only) with problems with women's hormones.

Despite these encouraging findings, other results from the same survey indicate that the percentage of consumers who acknowledge unhealthy eating behaviors is also increasing.

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[1] National Center for Health Statistics (NCHS). Report of final mortality statistics, 1995. Monthly Vital Statistics Report 45(11):Suppl. 2, June 12, 1997.

[2] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. National Cholesterol Education Program: Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). Circulation 89:1329-1445, 1994.

[3] U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (HHS). Dietary Guidelines for Americans. 5th ed. USDA Home and Garden Bulletin No. 232, 2000.

72% of shoppers *agree* or *strongly agree* with the statement, "I eat foods I enjoy, even if they're not good for me," up from 64% in 2001. 34% *agree* or *strongly agree* with the statement, "I eat whatever I want and don't think much about how it affects my health," up from 25% in 2001.

In addition, there is growing concern about obesity and appropriate health messages to address this unmet public health need. Persons who are overweight or obese are at increased risk for several chronic diseases.[4] In recent decades, there have been a number of public and private sector efforts in the United States aimed at reducing obesity. However, we have achieved only modest success with many of these efforts, and no success to date in reversing the alarming trend in the increase in overweight and obesity in this country. For example, in 1999, an estimated 61% of U.S. adults were overweight or obese, with nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980.[2] The tragic consequences of the current obesity epidemic have manifested themselves in premature death and disability, in increased health care costs, in lost productivity, and in social stigmatization. Approximately 300,000 deaths a year in this country are associated with overweight and obesity, with an estimated total cost of $117 billion in 2000.[2] Thus, finding more effective ways to improve consumer understanding and behavior is an urgent public health priority.

Although the scientific evidence in a number of substance/disease relationships does not, or might not, meet the standard of SSA, there is considerable evidence of a relationship between dietary choices and health and, in turn, a need to more fully inform consumers. For example, the following relationship, which may not meet the SSA standard, may be said to be based on somewhat settled science and therefore be important information for consumers: *Foods high in omega-3 fatty acids and the decreased heart disease risk.*

For the general population, in neither of these cases is there any significant evidence that a balanced diet low in total fat, saturated fat and cholesterol that includes consumption of these

[4] U.S. Department of Health and Human Services. 2002. The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville, MD: Public Health Service, Office of the Surgeon General. Available from : U.S. GPO, Washington.

foods presents safety or toxicity problems. Thus, even if only some of these apparently likely relationships are borne out in subsequent studies, greater consumer awareness of these relationships and changes in diet as a result would be expected to lead to significant public health benefits.

In addition, there is the opportunity to expand health messages beyond qualified health claims to dietary guidance. Public health priorities dictate a need for federal agencies and other stakeholders to partner to find useful and understandable health messages about general food choices and dietary patterns. For instance, FDA can partner with NCI in developing important messages about cancer. An example of such a dietary guidance statement from this Institute is: "*Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.*" This dietary guidance highlights a general category of foods and provides a valuable reminder to consumers about food choices.

Also, an increasingly important message for consumers is to substitute foods that decrease the risk of disease for those that do not, in order to build better diets. FDA can seek opportunities, using existing well-recognized government recommendations and partnerships, to identify the appropriate messages about food substitutions. For instance, the booklet "Dietary Guidelines for Americans" provides an important substitution health message about fats and heart disease: "*Substituting vegetable oils for solid fats may reduce your risk of heart disease.*"

Developments in the law, as well as critical public health considerations, are motivating this Initiative. Several of the substance/disease relationships for which FDA failed to find significant scientific agreement became the subject of a lawsuit, *Pearson v. Shalala* (*Pearson*), brought by a dietary supplement manufacturer. The plaintiffs in *Pearson* challenged FDA's general health claim regulations for dietary supplements, as well as FDA's decision not to authorize the health claims. The District Court ruled for FDA, but the U.S. Court of Appeals for the D.C. Circuit reversed the decision in 1999. The Court of Appeals ruled that the First Amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. The Court did not rule out the possibility that, where

evidence in support of the claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban the claim outright.

FDA's efforts to implement the Court ruling in *Pearson* have progressed through a series of steps. In order to provide for "qualified health claims," FDA issued a *Federal Register* notice in December of 1999 (64 FR 67289) outlining its plans to implement the ruling for dietary supplements. FDA updated its implementation plan in October 2000 (65 FR 59855), stating its intention to rely on enforcement discretion to provide for qualified health claims for dietary supplements.

In the December 20, 2002, *Federal Register*, the agency announced its intention to apply *Pearson* to conventional human food and provide for qualified health claims for such food. Recognizing the need for a regulatory framework to implement qualified health claims in light of the major scientific, public health, and legal developments of recent years, as well as the need both for scientific criteria to address the basis for qualified health claims and a better understanding of the nature of non-misleading claims on food labels, Commissioner McClellan formed the Task Force. The Task Force was given approximately six months to complete its work. The Task Force focused primarily on the issue of qualified health claims, but its discussions were enriched by considerations of promoting partnerships with sister public health agencies and others with the goal of improving the quality and impact of possible claims and labeling statements on conventional human foods and dietary supplements. Throughout the years, the federal government has worked to provide information to consumers about healthy eating patterns and wise food choices. Such advice originated with the Basic Four and has progressed through today's Dietary Guidelines for Americans and the Food Guide Pyramid. We expect that over time scientists will better understand these diet health relationships. As this happens, consumer actions based on this information should be encouraged and promoted by use of the food label.

An FDA determination concerning antioxidant vitamins and the reduced risk of certain cancers became the subject of a lawsuit known as *Whitaker v. Thompson*. In March 2000, the plaintiffs challenged FDA's refusal to permit the claim on dietary supplement products. FDA had determined that the evidence weighed more heavily against than in support of the relationship,

and that the claim was therefore inherently misleading. On December 26, 2002, the U.S. District Court for the District of Columbia disagreed. It found that the claim was only "potentially misleading," and that FDA should permit the claim with a disclaimer. In interpreting the earlier *Pearson* decision, the District Court also used a "credible evidence" rather than "weight of the evidence" standard in evaluating the claim before it. Claims for which evidence is merely credible would generally not be expected to benefit the public health as much as claims for which the evidence is stronger. For this reason and given the agency's limited resources, in setting priorities, FDA intends to take into account, among other things, the strength of the evidence supporting a claim.

The FDA Task Force on Consumer Health Information for Better Nutrition was established on January 16, 2003, as part of the Agency's Consumer Health Information for Better Nutrition Initiative. The Task Force includes representatives from FDA, the Federal Trade Commission and the National Institutes of Health. Commissioner McClellan appointed FDA Deputy Commissioner, Dr. Lester M. Crawford as the Task Force's Chair, and Mr. Joseph A. Levitt, Director of the Center for Food Safety and Applied Nutrition (CFSAN), as Vice Chair.

The Task Force was charged to develop a framework to help consumers obtain accurate, up-to-date, and science-based information about conventional food and dietary supplements. Specifically, the charge to the Task Force included the following:

- Report on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should apply the "weight of the evidence" standard established under the consumer health information initiative for qualified health claims in order to achieve these goals.

- Develop a framework for regulations that will give these principles the force and the effect of law. Identify procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of health claim petitions.

- Develop a consumer studies research agenda designed to identify the most effective ways to best present scientifically based, truthful and non-misleading information to consumers and to identify the kinds of information known to be misleading to consumers.

The Task Force met eight times from February 5 to June 20, 2003. At four of these meetings, groups of stakeholders representing health professionals, industry, the consumer community, and the academic and research community, respectively, were invited to provide the Task Force with ideas and insights. The participants at these stakeholder meetings are compiled in Attachment H of this report. At each of the four stakeholder meetings participants were asked whether they had any views on the following six general questions:

1. What body of scientific evidence do you think should be adequate for a qualified health claim?
2. What types of safety concerns should be factored into FDA decision-making?
3. What specific claims do you think are currently ready for consideration under the new guidance?
4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?
6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

A summary of each of these meetings is attached (Attachment H).

Contents of this Report

To address the various aspects of its charge, the Task Force has developed a series of documents that are included here as attachments. These are:

- Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
- Guidance: Interim Evidence-based Ranking System for Scientific Data
- Resources for Review of Scientific Data
- Consumer Studies Research Agenda – Improving Consumer Understanding on the Health Consequences of Dietary Choices
- Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
- "One-Year" Time Line for Qualified Health Claim Activities

Each of these documents is briefly summarized below. The full text of each is incorporated in the corresponding attachments to this report.

Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
(Attachment A to the Report)

This attachment presents three options or alternatives for FDA to consider for regulating health claims that do not meet the "significant scientific agreement" (SSA) standard of evidence by which the health claim regulations require FDA to evaluate the scientific validity of claims. The three are: (1) incorporate the interim procedures (Attachment E below) into a regulation pursuant to notice-and-comment rulemaking, (2) revise SSA to apply to accuracy of the characterization of the evidence supporting the claim (e.g., there is agreement that the data supporting a given claim are limited) and subject qualified claims to notice-and-comment rulemaking, and (3) regulate qualified claims solely on a post-market basis, completely outside the NLEA.

This attachment includes references to two additional documents that are also attachments to this report: (1) Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, and (2) Guidance: Interim Evidence-based Ranking System for Scientific Data. The Task Force recommends that FDA proceed on an interim basis under the guidances until the agency can promulgate regulations through notice-and-comment rulemaking.

Guidance: Interim Evidence-based Ranking System for Scientific Data
(Attachment B to the Report)

The interim evidence-based scientific ranking system laid out in this guidance (see Attachment B) describes a process for systematically evaluating the scientific evidence in support of a substance/disease relationship that is the subject of a qualified health claim. It provides a basis for evaluating the various attributes of the relevant data. The scientific ranking system provides a means by which the totality of the publicly available evidence can be assigned to one of four ranked levels. The highest level equates to significant scientific agreement for an

unqualified-health claim,[5] which is used as a point of reference but is outside the scope of this guidance. The remaining three levels would apply to qualified health claims. Various organizations have used evidence-based ranking systems with success, and the Task Force drew on these systems in devising the scientific ranking system.

The Task Force recommends that as FDA and stakeholders use the final guidance during this interim period, the agency assess the usefulness and limitations of such a system, and take this learning into account if, as the Task Force also recommends, it develops a proposed rule concerning an evidence-based ranking system for scientific data.

Resources for Review of Scientific Data

(Attachment C to the Report)

If FDA should receive a significant influx of new qualified health claim petitions, FDA may not be adequately staffed to conduct the scientific review of each such petition in a timely fashion. Although the agency will devote as many resources internally as possible to review of such petitions, it is incumbent on the agency to augment its limited review resources on an as-needed basis. To accomplish this, FDA will pursue a range of options for scientific review of data submitted in petitions in support of a substance/disease relationship. As a preliminary effort to enhance its ability to evaluate the scientific data that are a necessary part of providing for qualified health claims, FDA has executed a Task Order Request through an Interagency Agreement with the Agency for Healthcare Research and Quality (AHRQ). This Task Order will provide for review of specific scientific data as petitions are received. Evidence-Based Practice Centers (EPCs) selected through a competitive process will be assigned to review the scientific evidence for specified substance/disease relationships that are the subject of incoming petitions, prepare reports describing the evidence reviewed, an analysis of that evidence, a summary of and response to public comments that pertain to the evidence, and its assessment as to the degree of scientific certainty in support of the substance/disease

[5] The term, "unqualified health claim" is used in this report to refer to health claims that meet the Significant Scientific Agreement (SSA) standard and are or could be authorized under the Nutrition Labeling and Education Act (NLEA) and regulations promulgated under that Act including 21 CFR 101.70.

relationship. FDA will review the reports, and any of the evidence and public comments it deems necessary, and make a decision whether to exercise enforcement discretion.

FDA has recently taken steps to increase staff in its Center for Food Safety and Applied Nutrition (CFSAN) in order to expand its resources to address evolving issues in the area of applied nutrition. The Center has also recently created a senior level position, namely, Senior Advisor to the Center Director for Applied Nutrition that reports directly to the Center Director. This position complements the existing CFSAN staff including the Lead Scientist for Nutrition and the Director of the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS). Moreover, a separate division has been recently created within ONPLDS to focus more efficiently on nutrition related issues.

Consumer Studies Research Agenda – Improving Consumer Understanding and Product Competition on the Health Consequences of Dietary Choices
(Attachment D to the Report)

The ability to determine whether a qualified health claim does not mislead consumers is important in establishing a permanent process for qualified health claims. In order to ensure a successful program for accurate and understandable qualified health claims, it is essential to identify the appropriate words to convey to consumers in an understandable manner the different levels of science underlying different claims. To this end, a research agenda has been formulated to address these basic questions. This is an initial step in the process of gathering data about consumer understanding and effective ways to communicate health messages. Over time, the agency will consider opportunities to measure and evaluate consumer response and behavior relative to these messages.

Topics to be covered include the following research questions:

- Can consumers distinguish different levels of scientific support associated with qualified claims? How many levels can consumers distinguish?

- What are the appropriate words to convey different levels of scientific support to consumers? Do the qualifying words used in FDA's interim procedures signal different levels of scientific support to consumers; can they be improved? Can generic disclaimers be designed to convey the relative level of scientific support for qualified health claims?

- Are there additional aids (e.g., graphic formats and/or numbered or lettered rating designations) that could help consumers recognize the level of science that supports a qualified claim?

- Is there a difference in how consumers interpret and respond to qualified health claims on dietary supplements versus conventional foods?

The research design includes: (1) A mall-intercept experimental study of consumers' reactions to health claims and disclaimers for conventional foods and dietary supplements; (2) A focus group study of consumers' attitudes and feelings about different graphic formats intended to signal the level of scientific support for health claims; and (3) Three to five internet panel experimental studies to evaluate consumers' reactions to health claims and disclaimers for foods and dietary supplements.

Attachment D includes a description of proposed consumer research studies and a timeline for peer review of the protocol as well as OMB approval. A timeline has also been prepared to show the activities following OMB approval, including estimated time to conduct and evaluate the studies.

Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
(Attachment E to the Report)

This attachment sets out interim procedures the Task Force recommends that the agency use for qualified health claims in the labeling of conventional human food and dietary supplements

until the agency can promulgate regulations under notice-and-comment rulemaking, assuming the agency follows the Task Force's recommendation to issue such regulations.

The interim procedures describe a process for filing qualified health claim petitions; how to prioritize them in order to apply resources in the most effective and responsive way; opportunities for public comment; the procedures by which the agency may obtain third-party review of the assessment of the scientific data supporting a claim; as well as other procedural steps in health claim petition review. The Task Force recommends that, under its criteria for exercise of enforcement discretion, the agency begin applying these interim procedures for petitions submitted on or after September 1, 2003.

This guidance also provides a linkage between the ranking of scientific evidence and the wording of qualified health claims. The agency has chosen to designate the highest rank level of scientific evidence as an "A", corresponding to SSA, as a point of reference. Level "A" is otherwise outside the scope of this guidance. The remaining three levels are designated "B", "C," and "D," respectively (see Table below). FDA is providing standardized qualifying language for the B, C, and D categories to be used as part of the qualifying language for qualified health claims until consumer research (Attachment D) is completed.

SCIENTIFIC RANKING[1]	FDA Category	Appropriate Qualifying Language[2]
Second Level	B	... "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."

[1]From Final Guidance: Interim Evidence-based Ranking System for Scientific Data.

[2]The language reflects wording used in qualified health claims as to which the agency has previously exercised enforcement discretion for certain dietary supplements. During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary depending on the specific circumstances of each case.

"One-Year" Time Line for Qualified Health Claim Activities

(Attachment F to the Report)

A timeline has been prepared that consolidates the main activities that will be underway from June 30, 2003 through June 1, 2004.

Task Force Membership, Meetings, and Comments Summary

(Attachments G, H and I to the Report)

A list of the Task Force members, a summary of the four stakeholder meetings with representatives from health professionals, industry, consumer groups, and academic and research organizations, respectively; and a summary of selected comments submitted to the docket are included in the report.